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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,563	07/24/2001	Thomas P. Osypka	695716.0016 (OSCO-114)	6118
21874	7590	06/30/2004	EXAMINER	
EDWARDS & ANGELL, LLP			MAYNARD, JENNIFER J	
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BOSTON, MA 02205			PAPER NUMBER	

3763

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/911,563	Applicant(s) OSYPKA ET AL.	
	Examiner Jennifer J Maynard	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant's recitation of the flat distal end surfaces of the plug body and the port extending perpendicular to the longitudinal axis of the central lumen; and the flat annular distal surfaces of the plug body and the port being coplanar is not supported in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

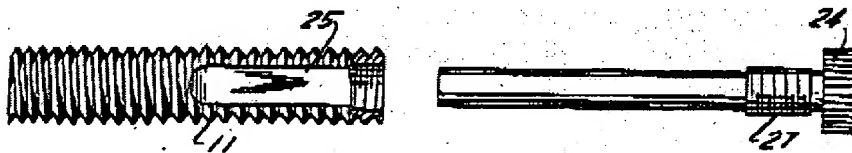
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeman (US 3,540,451 A).

Zeman discloses a drainage cannula with a threaded sealing pin comprising an access port defining an elongated tubular body (11) of predetermined length with a central lumen (25) bounded by a continuous, uninterrupted annular cylindrical outer wall, as shown in Figure 2, the tubular body having a longitudinal axis and opposed proximal and distal end portions (the proximal end is interpreted as the portion adjacent to overprotective button (22), while the distal

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end is labeled (11a)), the distal end portion of the tubular body adapted and configured for introduction into a blood vessel (even though this function is not specifically taught, the Examiner contends that there is sufficient structure to be capable of performing the function), the distal end portion of the tubular body defining a flat annular distal end surface (see Figure 1 or 2) extending perpendicular to the longitudinal axis of the central lumen; an elongated cylindrical plug (24) dimensioned and configured for insertion into the central lumen of the cannula and for ready removal therefrom, the plug body having a length that is substantially equal to the cannula, a longitudinal axis and a flat circular distal end surface extending perpendicular to the longitudinal axis of the plug body, see Figure 2, the flat circular distal end surface of the plug body preventing blood flow into the lumen of the cannula when the distal end portion of the access port is disposed within a blood vessel; and a locking mechanism (27) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (24) thereof for releasably coupling the plug body to the cannula, see Column 4, lines 8-10; Column 4, lines 26-28, and Figures 1 & 2.



Zeman fails to disclose the flat circular distal end surface of the port/cannula and the flat annular distal end surface of the plug body being coplanar.

It would have been an obvious matter of design choice to have made the plug body of sufficient length so as to extend at least the entire length of the port thus being flush with the port at their respective distal ends, so that the plug body fully occupies the inner lumen wall of the

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port, thereby ensuring that long-term placement of the port is not jeopardized by exposure of the port's lumen to bodily fluids which may result in obstruction of the port's lumen due to deposition or calcification of the fluids therein which would occur if the plug body were shorter than the port length. Additionally, the Examiner has failed to locate any criticality for the claimed structural limitation with respect to the flat annular distal surfaces of the plug body and the port being coplanar in Applicant's specification; and further the specification fails to address how the limitation solves any particular problem or serves any particular purpose, lending credence to the obviousness of the design choice.

Zeman discloses Applicant's claimed apparatus for facilitating vascular access with the exception of the plug body, handle portion and locking mechanism being formed monolithically.

It would have been a matter of obvious design/engineering choice to have formed Zeman's elongated cylindrical plug body, handle portion and locking mechanism monolithically as no criticality has been provided in the specification, nor has it been identified as solving any particular problem in the prior art, and the Examiner contends that the prior art device whose plug body, handle portion and locking mechanism are separately formed but joined together, would perform equally as well as if they were monolithically formed and as such would constitute an obvious design choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (US 4,318,401 A) in view of Zemen (US 3,540,451 A).

Zimmerman discloses a vascular access portal comprising a vascular access port (10) defining an elongated tubular body (14) of predetermined length with a central lumen (20) bounded by a continuous, uninterrupted outer wall, the tubular body having a longitudinal axis and opposed proximal and distal end portions (12, 30, respectively), and an inner diameter; the distal end portion of the tubular body is adapted and configured for introduction into a blood vessel and defining a flat annular distal end surface (30, see Figure 2) which may extend perpendicular to the longitudinal axis of the central lumen (not shown, see Column 4, lines 51-57) (which states that the upper flange (12) and stops (32, 74) may be angled with respect to the longitudinal axis, thus arranging the elongate portions of the port and plug body to be substantially perpendicular to the longitudinal axis of the device, or alternatively that the skirt (18, 26) could be parallel to the skin surface and thus be perpendicular to the longitudinal axis of the port); and an elongated cylindrical plug (22, 34) body dimensioned and configured for insertion into the central lumen of the vascular access port and for ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the length of the vascular access port, a longitudinal axis and a flat circular distal end surface (38, 40) extending perpendicular to the longitudinal axis of the plug body and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the vascular access port when the plug is engaged therein, the flat circular distal end surface of the plug body preventing blood flow into the lumen of the access port, and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body (see Figure 2); see Column 1, lines 63-68; Column 3, lines 3-5; Column 3, lines 14-20; and Column 3, lines 21-27.

Zimmerman disclose the invention as claimed with the exception of a locking mechanism, in the form of threads, associated with the proximal end of the elongated cylindrical plug body for coupling the plug body to the vascular access port; and wherein the plug body, handle portion and locking mechanism are formed monolithically.

Zeman discloses a drainage cannula with a threaded sealing pin comprising an access port defining an elongated tubular body (11) of predetermined length with a central lumen (25) bounded by a continuous, uninterrupted annular cylindrical outer wall, as shown in Figure 2, the tubular body having a longitudinal axis and opposed proximal and distal end portions (the proximal end is interpreted as the portion adjacent to overprotective button (22), while the distal end is labeled (11a)), the distal end portion of the tubular body adapted and configured for introduction into a blood vessel (even though this function is not specifically taught, the Examiner contends that there is sufficient structure to be capable of performing the function), the distal end portion of the tubular body defining a flat annular distal end surface (see Figure 1 or 2) extending perpendicular to the longitudinal axis of the central lumen; an elongated cylindrical plug (24) dimensioned and configured for insertion into the central lumen of the cannula and for ready removal therefrom, the plug body having a length that is substantially equal to the cannula, a longitudinal axis and a flat circular distal end surface extending perpendicular to the longitudinal axis of the plug body, see Figure 2, the flat circular distal end surface of the plug body preventing blood flow into the lumen of the cannula when the distal end portion of the access port is disposed within a blood vessel; and a locking mechanism (27) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (24) thereof for

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releasably coupling the plug body to the cannula, see Column 4, lines 8-10; Column 4, lines 26-28, and Figures 1 & 2.

It would have been obvious to one having ordinary skill in the art to have provided Zimmerman's vascular access portal with a locking mechanism, in the form of threads, as taught by Zeman, associated with the proximal end of the elongated cylindrical plug body for coupling the plug body to the vascular access port, so as to ensure that a hermetic seal remains intact during periods of non-use, thus avoiding contamination of the portal and inhibiting inadvertent removal of the plug prior to use thereof.

Zimmerman in view of Zeman disclose Applicant's claimed apparatus for facilitating vascular access with the exception of the plug body, handle portion and locking mechanism being formed monolithically.

It would have been a matter of obvious design/engineering choice to have formed Zimmerman in view of Zeman's elongated cylindrical plug body, handle portion and locking mechanism monolithically as no criticality has been provided in the specification, nor has it been identified as solving any particular problem in the prior art, and the Examiner contends that the prior art device whose plug body, handle portion and locking mechanism are separately formed but joined together, would perform equally as well as if they were monolithically formed and as such would constitute an obvious design choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Claims 25, 26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubert (US 3,572,333 A) alone, or in the alternative in view of Zimmerman (US 4,318,401 A).

Hubert discloses an apparatus for facilitating vascular access comprising a vascular access port (15) defining an elongated tubular body (16) of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having a longitudinal axis and opposed proximal and distal end portions, and an inner diameter; the distal end portion of the tubular body adapted and configured for introduction into a blood vessel ; and an elongated cylindrical plug (10, 12) dimensioned and configured for insertion into the central lumen of the vascular access port and for ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the vascular access port, a longitudinal axis, and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein; and a locking mechanism (27, 29) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (20) thereof for releasably coupling the plug body to the vascular access port, see Column 1, line 69 through Column 2, line 5; Column 3, lines 13-24 and Figures 1 and 2.

Hubert fails to disclose the access port having an elongated tubular body defining a flat annular distal end surface, and a plug having a flat circular distal end surface, so the flat annular end surface of the access port is coplanar with the flat circular distal end surface of the plug when the plug is inserted into the access port.

It would have been an obvious matter of design choice to have made the plug body of sufficient length so as to extend at least the entire length of the port thus being flush with the port at their respective distal ends, so that the plug body fully occupies the inner lumen wall of the port, thereby ensuring that long-term placement of the port is not jeopardized by exposure of the

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port's lumen to bodily fluids which may result in obstruction of the port's lumen due to deposition or calcification of the fluids therein which would occur if the plug body were shorter than the port length. Additionally, the Examiner has failed to locate any criticality for the claimed structural limitation with respect to the flat annular distal surfaces of the plug body and the port being coplanar in Applicant's specification; and further the specification fails to address how the limitation solves any particular problem or serves any particular purpose, lending credence to the obviousness of the design choice.

Alternatively, Zimmerman discloses a vascular access portal comprising a vascular access port (10) defining an elongated tubular body (14) of predetermined length with a central lumen (20) bounded by a continuous, uninterrupted outer wall, the tubular body having a longitudinal axis and opposed proximal and distal end portions (12, 30, respectively), and an inner diameter; the distal end portion of the tubular body is adapted and configured for introduction into a blood vessel and defining a flat annular distal end surface (30, see Figure 2) which may extend perpendicular to the longitudinal axis of the central lumen (not shown, see Column 4, lines 51-57) (which states that the upper flange (12) and stops (32, 74) may be angled with respect to the longitudinal axis, thus arranging the elongate portions of the port and plug body to be substantially perpendicular to the longitudinal axis of the device, or alternatively that the skirt (18, 26) could be parallel to the skin surface and thus be perpendicular to the longitudinal axis of the port); and an elongated cylindrical plug (22, 34) body dimensioned and configured for insertion into the central lumen of the vascular access port and for ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the length of the vascular access port, a longitudinal axis and a flat circular distal end

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surface (38, 40) extending perpendicular to the longitudinal axis of the plug body and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the vascular access port when the plug is engaged therein, the flat circular distal end surface of the plug body preventing blood flow into the lumen of the access port, and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body (see Figure 2); see Column 1, lines 63-68; Column 3, lines 3-5; Column 3, lines 14-20; and Column 3, lines 21-27.

It would have been obvious to one having ordinary skill in to have provided Hubert's vascular access port with an elongated tubular body having a flat annular distal end surface and plug with a flat circular distal end, so as that the flat annular end surface of the access port is coplanar with the flat circular distal end surface of the plug when the plug is inserted into the access port thus avoiding dead space which could lead to blood clotting therein and eventual thrombosis of the artery or vein.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubert (US 3,572,333 A) in view of Zimmerman (US 4,318,401 A).

Hubert in view of Zimmerman discloses Applicant's claimed apparatus for facilitating vascular access with the exception of the plug body, handle portion and locking mechanism being formed monolithically.

It would have been a matter of obvious design/engineering choice to have formed Hubert's elongated cylindrical plug body, handle portion and locking mechanism monolithically

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as no criticality has been provided in the specification, nor has it been identified as solving any particular problem in the prior art, and the Examiner contends that the prior art device whose plug body (12), handle portion (20) and locking mechanism (27, 29) are separately formed but permanently joined together, see Column 2, lines 13-15, would perform equally as well as if they were monolithically formed and as such would constitute an obvious design choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Response to Arguments

Applicant's arguments with respect to claims 25-32 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's arguments with respect to the 35 U.S.C. 103(a) rejection of Zimmerman in view of Zeman addressed on Pages 10-11 of Applicant's response. The Examiner directs Applicant to Zimmerman's Column 4, lines 51-57, which states that the upper flange (12) and stops (32, 74) may be angled with respect to the longitudinal axis, one skilled in the art would readily visualize that angling such portion relative the elongate portions of the port and plug body would result in the longitudinal axis being shifted so as to be substantially perpendicular to the both ends of the device, or alternatively that the skirt (18, 26) could be parallel to the skin surface and thus be perpendicular to the longitudinal axis of the port, which would make the plug body's and the port's distal ends being coplanar.

Further in response to Applicant's arguments with respect to the measurements of Zeman's drawings addressed on Page 11 of Applicant's response. Upon further review, the Examiner concurs with Applicant's assertion that Zeman's sealing pin/plug body is at least 2 mm

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longer than the hollow stem/port, however the Examiner contends that despite the slight discrepancy in length, that during use the flat annular distal end of the hollow stem/port would at some point during the insertion of the *longer* sealing pin/plug body into the hollow stem/port would result in the flat circular distal end of the sealing pin/plug body being coplanar with the flat annular distal end of the hollow stem/port. Additionally given the lack of criticality for the claimed structural limitation with respect to the flat annular distal surfaces of the plug body and the port being coplanar in Applicant's specification; and Applicant's failure to address how the limitation solves any particular problem or serves any particular purpose in the specification, lends credence to the argument that the limitation is a simple matter of obvious design choice.

Therefore in conclusion the Examiner has found Applicant's arguments unpersuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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